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10/535,270	02/09/2006	Rex W. Newkirk	101927/43	5756

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EXAMINER	
ML, QIUWEN	
ART UNIT	PAPER NUMBER
1655	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/535,270	NEWKIRK ET AL.	
	Examiner	Art Unit	
	QIUWEN MI	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 August 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 May 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment in the reply filed on 8/19/2010 is acknowledged. Claims 1-20 are pending. **Claims 1-20 are examined on the merits.**

Any rejection that is not reiterated is hereby withdrawn.

Claim Rejections –35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-20 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Siren (US 4,777,134), in view of Siren (US 4,797,390), further in view of Vanderbeke et al (US 5,554,399).

This rejection is maintained for reasons of record set forth in the Office Action mailed out on 2/19/2010, repeated below. Applicants' arguments filed have been fully considered but they are not deemed to be persuasive.

Siren (US 4,777,134) teaches (col 9, Example 12) a 10 gram quantity of sodium phytate (from corn Sigma Chemical Co) was dissolved in 500 ml sodium acetate, buffer at pH 5.0. With the temperature increased to 37.degree. C., wheat bran (thus a plant material containing a mixture of neutral sugars with a phytase enzyme) (10 g) was added at stirring (thus an aqueous

slurry). Incubation was started and continued at 37.degree. C. The dephosphorylation was followed by determining the inorganic phosphorus released. The hydrolysis was stopped by addition of 100 ml ammonia after 2 hours when 50% inorganic phosphorus had been liberated. The suspension obtained was centrifuged and the supernatant was collected (col 9, lines 42-50) (thus separating said slurry into a water soluble fraction and a water-insoluble fraction). Siren (US 4,777,134) also teaches 300 ml of the supernatant was passed through an ionexchange column (Dowex 1, chloride form, 25 mm.times.250 mm) and eluted with a linear gradient of hydrochloric acid (0-0.7N HCl). Aliquots of eluted fractions were completely hydrolyzed in order to determine the contents of phosphorus and inositol. Two fractions with the phosphorus/inositol (thus hydrolyzing the inositol phosphates in said first ionic fraction containing said mixture of neutral sugars), thus separating the hydrolyzed first ionic fraction into a second ionic fraction and a second neutral fraction which contains purified inositol) ratio of three to one (IP_3) (thus negatively charged, thus a partial hydrolysis) were collected (col 9, lines 54-62). According to the invention a procedure where a material containing IP.sub.6 is used is preferred as mentioned before. Then IP.sub.6 is broken down enzymatically to IP.sub.3 with phytase enzyme. Phytase enzyme is normally present in all inositolphosphate containing plants and seeds. Because of this it is, according to the invention, usually not necessary to add the enzyme if a natural product is used as starting material (col 3, lines 8-16). Even though Siren (US 4,777,134) does not explicitly teach adding phytase enzyme into the mixture in Example 12, as evidenced by Siren (US 4,777,134), phytase enzyme is normally present in all inositophosphate containing plants and seeds, thus the wheat bran contains phytase enzyme, and

the hydrolysis products of IP_3, inositol and phosphorus are the evidence of the presence of phytase enzyme.

Siren (US 4,777,134) does not teach the phytase enzyme includes acid phosphatase, the hydrolysis carried out at a pH of less than 4, separating the slurry into a water-soluble fraction and an insoluble fraction carried out by filtration, or hydrolyze inositol phosphates in first ionic fraction with acid phosphatease or phytase.

Siren (US 4,797,390) teaches that according to the invention a procedure where the above mentioned higher inositol phosphate IP.sub.6, IP.sub.5 and/or IP.sub.4 are broken down enzymatically to IP.sub.3 with phytase enzyme, for instance, is preferred. Phytase enzyme is normally present in all inositol phosphate containing plants and seeds. Because of this it is, according to the invention, usually not necessary to add the enzyme if a natural product is used as starting material. In the cases where the natural product has too low an enzymatic activity or when IP.sub.6, IP.sub.5 or IP.sub.4 or a mixture of these is used as starting material, a phytase enzyme, for example, from bran is added (page 4, lines 25-38). Siren (US 4,797,390) also teaches the content of the peak with the ratio of phosphorus to inositol of six to one was precipitated by addition of calcium hydroxide. The precipitate was filtered, washed and mixed with 10 ml of a cation-exchange resin to give the acid form of the inositolhexaphosphate. After neutralization with sodium hydroxide and freeze-drying the sodium salt of D-chiro-inositolhexaphosphate was obtained.

Vanderbeke et al teach an enzyme composition having a synergetic phytate hydrolyzing activity comprising a phytase having phytate hydrolyzing activity at a pH of from 2.5 to 5.0 and an acid phosphatase having phytate hydrolyzing activity at a pH of 2.5, in a low ratio

corresponding to a pH 2.5/5.0 activity profile of from 0.8/1.0 to 3/1. Said enzyme composition preferably displays a higher synergetic phytate hydrolyzing efficiency through thermal treatment (see Abstract). Vanderbeke et al also teach by using a mixture of acid phosphatase and phytase instead of phytase as sole enzyme, plant phytin hydrolysis is improved, not solely as a result of a higher thermostability of this enzyme mixture, but mainly as a result of an improved synergetic interaction between both enzymes as the ratio pH 2.5/5.0 phytate hydrolyzing activity will increase by the different thermal degradation of both enzymes (col 5, lines 60-67). Vanderbeke et al further teach most preferably the treatment is carried out at a pH of about 2.5 (thus less than 4).

It would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to either use the phytase enzyme that is normally present in all inositol phosphate containing plants and seeds to hydrolyze the inositol phosphates in the first ionic fraction, or newly add a phytase enzyme to hydrolyze the inositol phosphates from Siren (US 4,797,390) since Siren (US 4,797,390) teaches higher inositol phosphate IP.sub.6, IP.sub.5 and/or IP.sub.4 are broken down enzymatically to IP.sub.3 with phytase enzyme either naturally contained in the plants and seeds or freshly added when the enzyme level is low. It would also have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to use filtration to separate the slurry into a water-soluble fraction and an insoluble fraction as evidenced by Siren (US 4,797,390), filtration is a routine operation that is used in phytate hydrolyzation process.

It would also have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to include acid phosphatase with phatase from Vanderbeke et al to

hydrolyze phytate, phytic acid, phytin or inositol phosphates since Vanderbeke et al teach the enzyme composition displays a higher synergetic phytate hydrolyzing efficiency. It would also have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to treat the aqueous slurry at pH less than 4, since Vanderbeke et al teach preferably the treatment is carried out at a pH of about 2.5.

Since all the references yielded beneficial results in hydrolyzing phytate in plant materials, one of ordinary skill in the art would have been motivated to make the modifications to combine the references together.

From the teachings of the references, it is apparent that one of the ordinary skills in the art would have had a reasonable expectation of success in producing the claimed invention.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

Applicant argues that "The applicant respectfully disagrees that wheat bran contains a mixture of neutral sugars. A person of ordinary skill in the art would know that wheat bran is a by product of the wheat milling industry and that the bran is the hard outer layer of the grain and thus consists primarily of fiber. Wheat bran contains almost zero sugars and thus by adding wheat bran as the source of enzyme to the sodium phytate, one is not adding any significant amounts of sugar, *if any,* to the slurry (see for instance the "USDA National Nutrient Database for Standard Reference, Release 22 (2009)" a copy of which is attached for the Examiner's reference)" (page 6, 2nd paragraph). Applicant also argues that "In yet a further step in Example 12, after partial hydrolysis, the resulting supernatant is passed through a column and eluted with

increasing concentrations of HCl in order to displace the inositol phosphates. Eluted fractions are then hydrolyzed for the purpose of identifying the various inositol phosphates. However, the mixture that is passed through the column is simply a mixture of inositol phosphates without the neutral sugars. As such, Siren is merely measuring the various forms of inositol phosphates in order to quantify them and detect IP3" (page 6, 3rd paragraph). Applicant further argues that "When contrasted with claim 1 of the present invention, step (a) is not taught since there is no treatment of an aqueous slurry of plant material containing a mixture of neutral sugars. The wheat bran is not the starting material that is the subject of the "treatment" or partial hydrolysis as per claim l(a). Rather the starting material is sodium phytate which is not a plant material that contains any neutral sugars. Moreover, the addition of wheat bran to the purified sodium is being added merely for its phytase activity and is not likely to add any sugars to the mixture" (page 6, last paragraph). Applicant argues that "Step (c) is not present since Example 12 does not separate the water soluble fraction into a first ionic fraction from another neutral fraction which contains neutral sugars. Furthermore, step (e) of claim 1 is not taught in Siren since the step of isolating the inositol from the other charged components is not disclosed" (page 7, 1st paragraph).

This is not found persuasive. Numerous publications teach wheat bran contains neutral sugars. For instance, Chen et al (Chen et al, Mechanisms by which wheat bran and oat bran increase stool weight in humans, Am. J. Clin. Nutr 1998; 68: 711-9) teach the composition of the dietary fiber in wheat brans (Table 3, page 715). Chen et al teach wheat bran contains glucose, xylose, galactose, arabinose and mannose. The total neutral sugars in soluble fraction of wheat bran is 1.4%; and the total neutral sugars in insoluble fraction of wheat bran is 41.3% (Table 3, page 715). Nyman et al (Nyman et al, Fermentation of dietary fiber in the intestinal tract:

comparison between man and rat, British Journal of Nutrition (1986), 55, 487-496) teach dietary fiber in wheat bran contains 133 g/kg arabinose, 183 g/kg xylose, 3 g/kg mannose, 11 g/kg galactose, 169 g/kg glucose, and the sum of neutral sugars is 499 g/kg in dietary fiber of wheat bran (page 490, Table 1). Also Anderson et al (Anderson et al, Dietary fiber content of corn bran, Journal of Food Protection, 43 (10): 760-762) teach the cellulose extract of the wheat contains neutral sugar fraction, 1.6 ± 1.1% arabinose, 9.3 ± 1.5% xylose, 1.8 ± 0.3% mannose and 87.2 ± 1.8% glucose (page 761, 2nd column, 2nd paragraph). Furthermore, Theander et al (Theander et al, Studies on dietary fibers. 1. Analysis and chemical characterization of water-soluble and water-insoluble dietary fibers, Swedish Journal of Agricultural Research (1979) 9 (3): 97-106) teach the water-soluble fraction of wheat bran contains 2.1% neutral sugars (page 103, Table 1) and the water-insoluble fraction of wheat bran contains 28.3% neutral sugars (page 103, Table 2). Therefore, wheat bran does contain neutral sugars, and thus the limitation of the claims are met.

Applicant argues that "The Examiner has further cited Siren 2 at page 4 of her Report on the basis that phytase enzyme is normally present in all inositol containing plants and seeds and is therefore not necessary to add enzyme if a natural product is used as a starting material Applicant notes that Siren 2 teaches adding a phytase enzyme to a mixture of higher inositol phosphates to break them down to IP3. However, Siren 2 does not teach the present invention, and also does not teach steps (c) and (e) taught by claim 1 of the present invention that are missing from Siren. Applicant also submits that using the phytase enzyme that is normally present in all inositol phosphate containing plants is not always feasible, especially in cases

where the starting material has little to no naturally occurring phytase activity" (page 7, 2nd paragraph).

This is not found persuasive. It would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to either use the phytase enzyme that is normally present in all inositol phosphate containing plants and seeds to hydrolyze the inositol phosphates in the first ionic fraction, or newly add a phytase enzyme to hydrolyze the inositol phosphates from Siren (US 4,797,390) since Siren (US 4,797,390) teaches higher inositol phosphate IP.sub.6, IP.sub.5 and/or IP.sub.4 are broken down enzymatically to IP.sub.3 with phytase enzyme either naturally contained in the plants and seeds or freshly added when the enzyme level is low. It would also have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to use filtration to separate the slurry into a water-soluble fraction and an insoluble fraction as evidenced by Siren (US 4,797,390), filtration is a routine operation that is used in phytate hydrolyzation process.

Applicant argues that "The core of the present invention is to utilize a method for the partial hydrolysis of phytate to charge intermediates, separate these negatively charged intermediates from the neutral sugars in solution and then complete the hydrolysis to generate neutral inositol that can be readily separated from charged ions and compounds using known charged based separation techniques. The elements of claim 1 and dependent claims 2-20 are not taught or disclosed by Siren or Siren 2 individually, nor by the combination of Siren and Siren 2" (page 7, 3rd paragraph). Applicant also argues that "The Examiner has further cited Vanderbeke at page 5 of her Report against the present invention. However, Vanderbeke merely teaches that full hydrolysis is possible with an optimized enzyme

composition that displays a higher synergistic phytate hydrolyzing activity at a pH from 2.5 to 5.0 and an acid phosphatase having phytate hydrolyzing activity at a pH of 2.5. Vanderbeke in and of itself does not teach the steps disclosed in claim 1 of the present invention nor what is missing from Siren and Siren 2" (page 7. last paragraph).

This is not found persuasive. As mention above, the wheat bran in Siren contains neutral sugars, thus Siren and Siren 2 do teach the claimed invention.

Applicant's arguments have been fully considered but they are not persuasive, and therefore the rejections in the record are maintained.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Qiuwen Mi whose telephone number is 571-272-5984. The examiner can normally be reached on 8 to 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Qiuwen Mi/

Primary Examiner, Art Unit 1655